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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/441,654	11/12/99	CHAN	MSB-7263

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HM12/0424

EXAMINER

BUGAISKY, G

ART UNIT

PAPER NUMBER

1653

10

DATE MAILED: 04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/441,654

Applicant(s)
CHAN et al.

Examiner
Gabriele E. Bugalsky

Group Art Unit
1653



☒ Responsive to communication(s) filed on Dec 26, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 2-9 and 15-21 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2-9 and 15-21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Applicant's election of Group II (claims 2-9 and 15-21) and cancellation of non-elected claims in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The disclosure is objected to because of the following informalities: on page 13, line 25, the ATCC accession number is blank..

Appropriate correction is required.

Applicants are requested to amend their reference to pending US applications should patents issue therefrom.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawaguchi *et al.*

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Kawaguchi *et al.* provides for purification of human hepatocyte growth factor activator inhibitor type 2 from conditioned medium of MKN45 cells. The reference is deemed anticipatory for the claimed subject matter because the primary amino acid sequence of human hepatocyte growth factor activator inhibitor type 2 is identical to instant SEQ ID NO:1 and because the protein is purified from human cells, it inherently is glycosylated ; indeed, for SDS-PAGE analysis, the protein is deglycosylated (see last paragraph, column 1, page 27550) . With respect to the recited pharmaceutically acceptable carrier, the protein activity was assayed in PBS.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentz *et al.* in view of Gribben *et al.* and Hotchkiss *et al.* The Gentz reference provides for production of TFPI-3, a two domain Kunitz protein inhibitor. Its sequence is identical to SEQ ID NO:1. In example 5, the first Kunitz domain is assayed. That domain was produced by *E. coli* and not by

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mammalian cells. Gribben *et al.* show that antibodies develop to recombinant human GMS-F that is not glycosylated and Hotchkiss *et al.* show that the carbohydrate structure of recombinant tissue factor plasminogen activator has an effect on the rate of clearance. Neither examines glycosylated TFPI-3. In order to provide the domain 1 of Gentz *et al.* in a form that neither elicits antibodies & has a relatively long half life, it would have been obvious to one of ordinary skill in the art at the time of the invention to express domain I in mammalian cells, with a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 5:50 AM to 11:50 AM on Mondays and from 8:00 AM to 2:00 PM on other weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

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Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.



Gabriele E. Bugaisky

Patent Examiner

4/5/01